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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/125,114	08/18/1998	IAN ASHLEY PRICE	P8129-8004	7439

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ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

EXAMINER	
SHARAREH, SHAHNAM J	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 01/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/125,114	PRICE, IAN ASHLEY	
	Examiner	Art Unit	
	Shahnam Sharareh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-15,20-25,32-37 and 39-73* is/are pending in the application.

4a) Of the above claim(s) *11-15,20-25,32-37 and 48-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-47 and 52-73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Amendment filed on October 24, 2005 has been entered. Claims 11-15, 20-25, 32-37, 39-73 are pending in this application. Claims 11-15, 20-25, 32-37, 48-51 are withdrawn from further consideration. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01. Claims 39-47, 52-73 are under consideration.

Applicant's arguments, filed on October 24, 2005, with respect to the rejection(s) of claim(s) 38-47, 52-73 under 35 USC § 103 have been considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Armitage and Gruber Patents.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 39-47, 52-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over in view of Armitage et al US Patent 5,696,165 in view of Arvanitidou et al WO 96/19982 (IDS, March, 2000).

The scope of the instant claims are directed to solid compressed compositions comprising racemic ibuprofen in the form of sodium salt in amount of at least 35% by weight of the composition, a compressible filler combined with a disintegrant, and sodium carbonate in amount of about 3-20%. The claimed composition also contains various functional limitations, which are either attributed to its intended use or its

process of making. For example the recitation of "non-effervescent" dosage form is viewed as an intended use limitation because once the individual components of the instant claims are described in a prior art composition, the prior art composition is expected to provide the claimed intended use.

The limitations directed to compression force and crushing strength are also directed to the process of making the dosage form. Examiner states composition claims that are drafted as "product by process" are not limited to the manipulations of the recited steps, only the structure implied by the steps. (see MPEP 2113). "Even though product - by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product - by - process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

Thus, Applicant is placed on notice that the recited functional limitations do not appear to affirmatively limit the scope of the claimed composition.

Armitage teaches solid compositions comprising sodium salt of racemic ibuprofen and sodium carbonate in the form of granules (see col 16, example 18). The formulation of Armitage contains 16.5% ibuprofen salt and 4.6 % of sodium carbonate. The granule formulations of Armitage can have up to about 99% ibuprofen, therefore, Armitage teaches the concentrations of the instant claims. (see col 22, lines 24-37). Armitage further teaches the use of fillers and disintegrants in his formulations including

lactose, croscarmellose, cyclodextrin, etc...(see col 22, lines 20-40; col 2, line 66-col 3, line 43). Armitage further teaches film coating of his oral compositions (see col 15-17). Armitage's granules are described as effervescent granules because they contain malic acid. however, since Armitage's composition contains all components of the instant claims, it can also be used as a non-effervescent formulation with or without the malic acid. Armitage only fails to describe the compression characteristics of the instant compositions.

However, it would have been obvious to one of ordinary skill in the art at the time of invention to optimize the compression force and crushing strength by routine experimentation to formulate a commercially and therapeutically feasible composition.

3. Claims 39-47, 52-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Armitage et al US Patent 5,696,165 in view of Arvanitidou et al WO 96/19982.

The teachings of Armitage are described above. Armitage does not explicitly that his granules can be used in as a non-effervescent formulation.

Arvanitidou is merely used to show that preparing a non-effervescent ibuprofen composition is well recognized in the art and readily employed to prepared ibuprofen containing compositions (see pages 5-6; page 7 last para). Arvanitiodou teaches methods of making non-effervescent compositions comprising ibuprofen and an inorganic alkaline salt such as sodium carbonate (see page 5, last para; page 9, examples I-V). Arvanitiodou describes that converting the non-effervescent formulation to an effervescent formulation merely requires the addition of an organic acid such as

citric acid or malic acid (see page 7, 2nd para and page 9, last 3 lines). Arvanitiodou only fails to use a racemic ibuprofen salt form.

Nevertheless, it would have been further obvious to one of ordinary skill in the art at the time of invention to merely eliminate the malic acid of Armitage granules to formulate a non-effervescent solid formulation for any patient preferring non-effervescent formulations of ibuprofen. The ordinary skill in the art would have had a reasonable expectation of success, because as shown by Arvanitidou, adding an organic acid to non-effervescent formulations of Ibuprofen to convert a non-effervescent formulation to an effervescent formulation is conventional and well within purview of one of ordinary skill in the art.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHENGJUN WANG
PRIMARY EXAMINER

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